

510(k) Summary: Endo-Therapeutics Endo-Glide Guidewires

- (1) Endo-Therapeutics Inc.
1183 Cedar st.
Safety Harbor, FL 34695

FEB 19 2003

Contact Person: Todd Adkisson
Date Prepared: 9/2/02

510(k) #: K

- (2) **Trade or Proprietary Name:** Endo-Glide Guidewire
Common Name: Guidewire
Classified Name: Gastrointestinal Guidewire

- (3) **Equivalent Predicate Devices:**
Jagwire™ Guidewire (K922302),
Flex Finder® Guidewire (K964955),
Next Generation Guidewire (K011759)

- (4) **Description of Device:**
The Endo-Glide Guidewire has a range of diameters from 0.025" to 0.035" and lengths from 250cm to 450cm. The wires are offered with and without a 50mm radiopaque platinum distal tip (curved and straight). The wires are assembled with a solid nitinol or stainless steel core wire, which can be tapered at the distal tip. A lubricious coating (PTFE or hydrophilic) surrounds the entire core and/or tip, which also provides insulation.

- (5) **Intended Use:**
Endo-Glide Guidewire is used for selective cannulization of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

- (6) **Technological Characteristics:**
The Endo-Therapeutics Endo-Glide Guidewires have essentially the same technological characteristics as the predicate device. The intended use, design, materials and method of operation are all substantially similar to the before mentioned guidewires.



FEB 19 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Todd Adkisson
Endo-Therapeutics Inc.
1183 Cedar Street
Safety Harbor, FL 34695

Re: K023603
Trade/Device Name: Endo-Glide Guidewire
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope
and accessories
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter
and accessories
Regulatory Class: II
Product Code: 78 KOG/GCA
Dated: January 23, 2003
Received: January 27, 2003

Dear Mr. Adkisson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

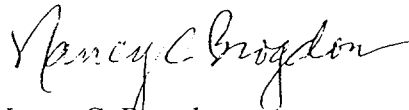
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K 023603

510(k) INDICATIONS FOR USE STATEMENT

510(k) Number (If KNOWN): K 023603

Device Name: Endo-Glide Guidewire

Applicant Name: Endo-Therapeutics, Inc

Indications for Use: Endo-Glide Guidewires are intended to be used for selective cannulization of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

Signature:



President

Date:

9/2/02

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 
(Per 21 CFR 801.109)


(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K023603